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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,077	12/29/2005	Ernest P. Noble	UCLA.154-US-WO	3519

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EXAMINER	
LUNDGREN, JEFFREY S	

ART UNIT	PAPER NUMBER
1639	

NOTIFICATION DATE	DELIVERY MODE
06/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/563,077	NOBLE ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Lundgren	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *3 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-8 are pending in the instant application; claims 3 and 4 are withdrawn as being directed to a non-elected species; claims 1, 2 and 5-8 are the subject of the Office Action below.

Claim Rejections - 35 USC § 112, first paragraph (New Matter) – Maintained

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 2 and 5-8, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for containing new matter, is maintained. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants allege that although the specification provides the erroneous statement in direct contradiction to what is being claimed, that one of ordinary skill in the art would have understood from the experimental data provided, that the currently claimed invention finds full support. Applicants allege that Example 1 provides evidence that supporting their conclusion that the claimed "high dose high binding atypical antipsychotics" should be used on patients who are A1- and "low dose low DRD2 binding atypical antyipsychotics" should be used A1+ patients.

The Examiner disagrees. First, the results shown in Applicants specification relate to a scoring system directed towards Parkinson's disease, not "psychiatric" disorders, which is what the currently claimed invention is directed towards, nor how the scoring is relevant to the claimed invention. Second, the drug being studied in Example 1 is risperidone, and does not generally support a sufficient genus to support the claim breadth (*i.e.*, all high dose high binding atypical antipsychotics, as this example does not contemplate such an embodiment).

Applicants further allege that the data for Example 3 is "unambiguous" to one of ordinary skill in the art, and would support the claimed invention. Applicants point to the data in Figure 6 and the supporting Declaration, and certain publications which Applicants allege supports the validity of their conclusions.

The Examiner disagrees. Again, the experimental findings do not fully support the full breadth of the claim, especially in view of the direct contradiction of the generic statement in the specification. The compound of study in Example 3 is only a single compound, namely, paroxetine, a single SSRI. There is no comparison of a "high dose high binding atypical antipsychotics" under the measure of GHQ, nor is there a study showing "low dose low DRD2 binding atypical antipsychotics". Both of these categories of compounds are set forth in the claim.

Further, contrary to the evidence provided by Applicants, it appears that those of ordinary skill in the art doubt the reliability of the GHQ score, therefore making Applicants assertions that one of ordinary skill in the would find the data in the specification supportive of the claimed invention. For example, see the publication by Willmott[1].

Even if the GHQ score was accepted, at best it appears that the only statistically significant measure would be for the treatment of "social dysfunction and anxiety" in A1+ patients. However, the claim is directed towards all psychiatric disorders.

Again, as mentioned previously and reiterated here again, these limitations are in direct contradiction to Applicants provisional application (see first paragraph under Summary of the Invention on page 1; see also claim 1 on page 53), their published International Application WO 2005/007871 A2 (paragraph 0004), and the current specification. Specifically, the specification states:

> "The invention provides methods of identifying candidate psychiatric patients or patients with movement disorder for treatment with medication that acts at the D2 dopamine receptor. The method comprises determining a patient's D2 dopamine receptor DRD2) genotype. Patients having the Taq1A (A1) allele ***(A1+ allelic status) are candidates for treatment with high dose of high D2 dopamine receptor binding antipsychotics*** and/or SSRIs that influence D2 dopamine receptor density. Patients lacking the Taq1A allele ***(A1- allelic status) are not likely to respond well to these***

[1] Willmott *et al.*, *Soc. Psychiatry Psychiatr Epidemiol*, *39*:613-617 **(2004).**

> ***SSRIs, and are candidates for treatment with <u>lowdose</u> of low D2 dopamine receptor binding or low dose high D2 dopamine receptor binding atypical antipsychotics.***"

Specification, paragraph 0004 (emphasis added).

The specification provides the following definitions:

> "As used herein, "high dose" of medication means more than the chlorpromazine equivalent per kilogram (kg) of body weight (CPZEK) of about 10. (Given an average adult patient body weight of 70 kg.) One mg risperidone is equipotent to 100 mg chlorpromazine, 100 mg thioridazine, or 2 mg haloperidol. For example, a high dose of risperidone is about 6 mg/day or more for an adult patient.
>
> As used herein, "high D2 dopamine receptor binding" or "high binding" antipsychotics means having an affinity for the D2 dopamine receptor exhibiting a K_i of less than 10 nM, as measured by in vitro radioligand binding (See, .g., Levant, 1997, Pharmacological Reviews, 49(3):231-252). This class of antipsychotic medications is often referred to in the art as "typical" antipsychotics. Representative examples include rispetidone (resperidone), flupenthixol, gluphentazine decanoate, zuclopenthixol, haloperidol, thiondazine, thiotthixene and trofluperazine.
>
> As used herein, "low dose" of medication means less than a CPZEK of less than about 7. For example, a low dose of risperidone is less than about 5 mg/day for an adult patient.
>
> As used herein, "low D2 dopamine receptor binding" or "low binding" antipsychotics means having an affinity for the D2 dopamine receptor exhibiting a K_i of greater than 15 nM, as measured by in vitro radioligand binding (See, e.g., Levant, 1997, Pharmacological Reviews, 49(3):231-252). This class of antipsychotic medications is often referred to in the art as "atypical" antipsychotics. Representative examples include Olanzapine and Clozapine."

Specification, paragraphs 0017-0020.

It is still the Examiner's position that Applicants have relied on a selective interpretation of the specification in finding support. Although there is some support in the discussion of the specification that could *possibly* be construed to support the claim language, the direct contradiction of the specification as cited above, and the vague experimental data (e.g., data for

Figures 5 and 6), do not clearly convey that the sections of the specification at paragraphs 0004 and 0017-0020 were simply typographical errors.

The rejection is maintained.

Conclusions

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey S. Lundgren/
Primary Examiner, Art Unit 1639